Remarks

Currently Claims 9-12 are pending. Applicants acknowledge with appreciation the Examiner's indication that the claims are patentable over the prior art.

Section 112, First Paragraph Rejection Overcome

Claims 9-12 currently stand rejected under 35 U.S.C. section 112, first paragraph, the Office Action stating that the specification, while being enabling for the treatment of IBS and epilepsy does not reasonably provide enablement for the prophylaxis of these conditions. Applicants respectfully traverse this rejection.

The proper test for enablement is whether the disclosure contains sufficient information to allow one skilled in the art to carry out the claimed invention without undue experimentation. The specification teaches how to make the compound at page 8, line 24 through page 18; and how to administer the compound, including pharmaceutical formulations, dosages and various routes of administration at page 6, line 9 through page 8, line 22 and page 18, line 1 through page 19. The Examiner appears to agree that the specification teaches how to make and administer the compound inasmuch as the enablement for *treatment* has been acknowledged. The method one skilled in the art would use for the treatment of IBS or epilepsy is the same as the method that would be used for prophylaxis. That is, for either treatment or prophylaxis, one skilled in the art would administer the recited compound. Given that the methods for making and administering the compound are the same for either treatment or prophylaxis of the recited conditions, a specification enabling for treatment is necessarily enabling for prophylaxis as well.

The burden for establishing a *prima facie* case of non-enablement rests with the Examiner. MPEP 2164.04. A specification which contains a teaching of

the manner and process of making and using an invention in terms which correspond in scope to those in the claims must be taken as enabling under Section 112, unless there is a reason to doubt the objective truth of the statements in the specification. *Id.* In the instant case, the Office Action fails to provide any explanation why one skilled in the art would reasonably doubt that the methods described by Applicants for making and administering the recited compound would not be equally applicable for both methods of prophylaxis and methods of treatment. Accordingly, the Office Action fails to meet the burden of establishing a *prima facie* case of the non-enablement of the claims.

The Examiner appears to be focused upon whether the claimed compounds will be *effective* for the "prevention" of the stated condition.

> "It has not been shown in the specification that the **"prophylaxis"** of such disease is accepted in the art..." Office Action mailed 28 Oct 2004, emphasis original.

This is not the proper standard for enablement under section 112. Preliminarily, the term "prophylaxis" in its customary usage, includes protective treatment for disease. Thus, prophylaxis refers, *inter alia*, to the prevention of some or all symptoms in an afflicted subject, or the prevention of recurrence of symptoms in a previously afflicted subject –i.e., protective treatment. The Examiner's analysis of the Wand's factors is flawed in that it appears to based on a flawed interpretation of the claim requiring the complete prevention of the stated condition. That a particular disease cannot be completely prevented based on current scientific knowledge in no way establishes that the occurrence or recurrence of some or all symptoms of the condition cannot be prevented. All that is necessary for carrying out the claimed method for prophylaxis is administration of the compound, which the Examiner has already conceded is enabled by Applicants' specification.

Moreover, whether or not a stated condition may be prevented by

conventional medical knowledge or whether the compounds of the invention will be effective for such prevention is not the proper standard under 112, first paragraph. The burden is not on Applicants to substantiate every asserted use or to prove efficacy for claimed therapies. To the contrary, absent objective evidence to the contrary, it is improper for the Patent Office to question the truth of the disclosure as to enablement. MPEP 2164.04. In particular, the MPEP makes clear that it is not the province of the Examiner to evaluate the efficacy of the compounds in the claimed methods. MPEP 2107.02. Given that so much of the Examiner's remarks appear to be directed toward doubts of utility rather than how to practice the invention, perhaps the Examiner intended to make a lack of utility rejection under 35 U.S.C. §101? (See MPEP 2164.07). However, since no such rejection is on the record, Applicants will not address utility at this time.

Given that the Office Action fails to provides any objective evidence that the administration methods described must some how be different for methods of treatment versus methods of prophylaxis, Applicants respectfully submit that the Office Action has not established a *prima facie* case of non-enablement and withdrawal of this rejection is respectfully requested.

Applicants respectfully note that the same rejection was made and overcome in parent patent application no. 10/148,434, now granted patent no. 6,713,491, which includes claims reciting the same language for other conditions.

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Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at 483-8222, to discuss this case, if desired.

Respectfully submitted,

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